January 14, 2000

8674 '00 JAN 18 A9:48

Food and Drug Administration
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
5603 Fishers Lane
Room 1061(HFA-305)
Rockville, MD 20852

Docket number 99N-4491

Re: Reprocessing and Reuse of Single Use Devices – Risk Categorization Scheme

This is in response to the December 9,1999 FDA release on the reprocessing of single use devices.

Vital Signs Inc. is a leading U.S. manufacturer of single patient use Anesthesia Breathing Circuits. An Anesthesia Breathing Circuit was used as an example in the proposed "Reprocessing and Reuse of Single Use Devices - Risk Categorization Scheme" (to be referred to as RCS). Although the RCS has merit to address the serious issues raised by reprocessing medical devices, it is clear that it is flawed, at least as to this example.

The example states that "an Anesthesia Breathing Circuit device consists of flexible or rigid tubing that is used to convey gases to the patient. It is indirect-patient contact and is usually constructed of PVC." First, by properly describing even the most simple of single patient use Anesthesia Breathing Circuits (ABC SUD) that are in use today would lead one to a different risk category. ABC SUD tubing is "corrugated" and does not have a smooth lumen, making cleaning difficult. The tubing is not made of PVC and is not rigid. Secondly, ABC SUD tubing not only "conveys" gases to the patient, but also transports exhalation gases away from the patient. This presents a source of "contamination".

Further, even the simplest of ABC SUDs in use today also have a wye connector of some fashion to which the inspiratory and expiratory limbs connect and this, in turn, connects to the patient via a mask or endotracheal tube. It is essential that these tube connections be secure to reduce any risk of an accidental disconnect during use, and have minimal leakage. These requirements are specified in ASTM F1205, Standard Specification for Anesthesia Breathing Tubes. To achieve this, there are interlocking and inaccessible areas where the tubes join the connector, which would make cleaning or sterilization difficult. To improve its' "cleanability," someone might disconnect the tubes from the connector, clean/sterilize it and reassemble it. Their handling would jeopardize performance by increasing the risk of leakage and inadvertent disconnection during use on a patient. The security of assembly and the need for "leak free" can not be assured by visual inspection.

20 Campus Road, Totowa, N.J. 07512 • 1-800-932-0760 • N.J. 973-790-1330 • Fax: 973-790-3307

99N-4491

C100

vital signs inc.

Finally, many ABC SUDs have a heat and moisture exchanger (HME), a facemask and or a filter attached as well as a supplied reservoir bag. Filters and HMEs can not be cleaned or sterilized without affecting their performance. HMEs will, because of their hygroscopic properties, readily absorb disinfecting or cleaning solutions and or sterilants, which would present a significant risk to a patient through inhalation. Some filters have built-in electrostatic properties that can be destroyed by cleaning, and thus the filter efficiency compromised. Both of these components could see a dangerously high increase in resistance and cause the patient difficulty in exhalation and/or inhalation. Applying the RCS scheme and reaching the right conclusion is difficult. As discussed above, if one is not careful and diligent, the FDA would have all breathing circuit configurations in a "low risk" category when even the simplest one should properly be categorized as high risk.

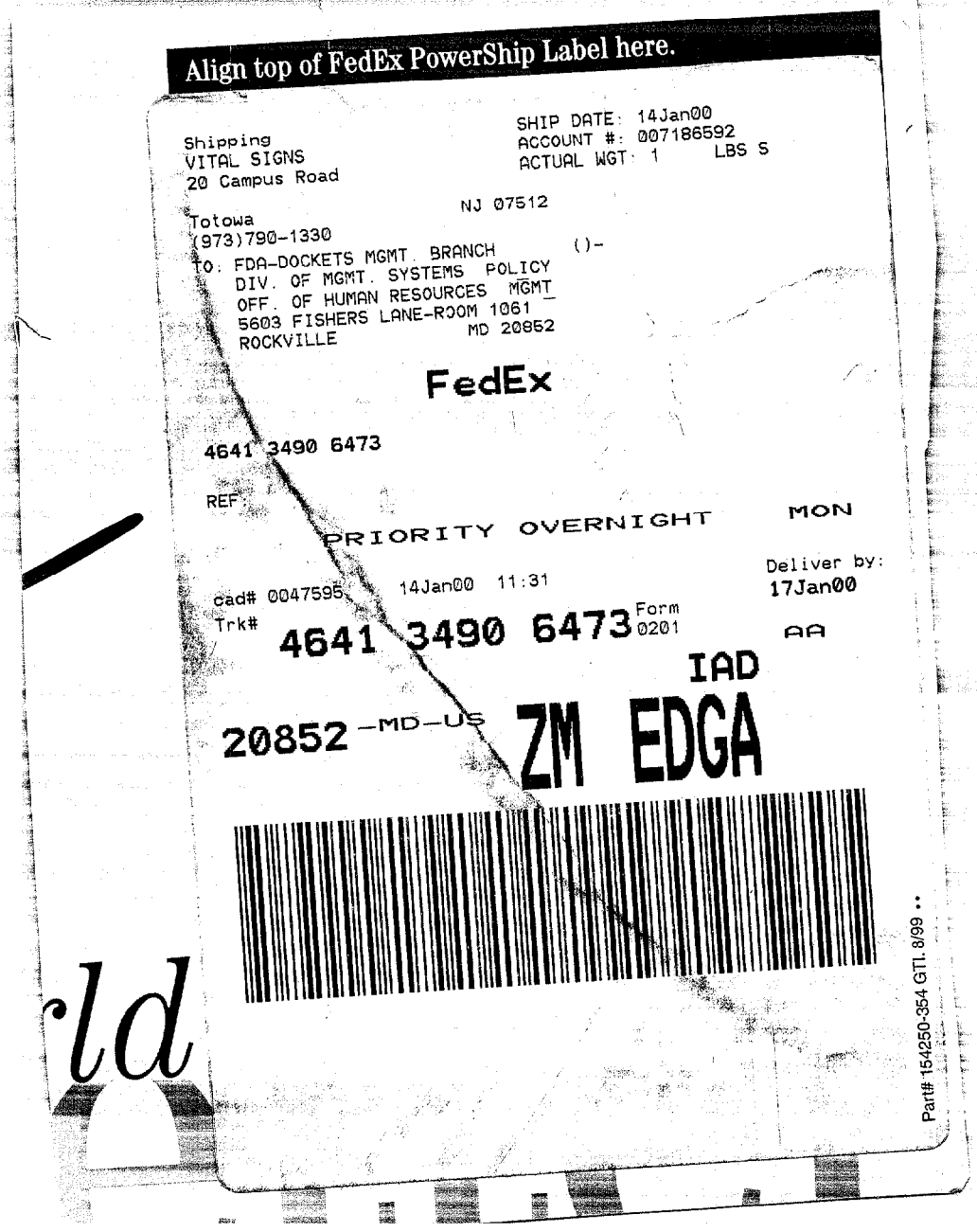
We believe the example you selected for a low risk scenario is not an appropriate one. The complexities of ABC SUDs described above require that this device be considered high risk. This example also highlights the need that the individuals doing the "categorizing" need to have input from health care professionals, infection control and other industry experts.

We would be pleased to discuss this further with you at your convenience. I may be reached at (973) 790-1330, ext. 356 or email **tmartino@vital-signs.com.**

Sincerely,
**VITAL SIGNS, INC.**

Anthony P. Martino
VP Quality Assurance and Regulatory Affairs

CC: Josephine M. Torrenet, President
Association of Disposable Devices Manufactures


Align top of FedEx PowerShip Label here.
Shipping
VITAL SIGNS
20 Campus Road
Totowa NJ 07512
(973)790-1330
SHIP DATE: 14Jan00
ACCOUNT #: 007186592
ACTUAL WGT: 1 LBS S
()-
To: FDA-DOCKETS MGMT. BRANCH
DIV. OF MGMT. SYSTEMS POLICY
OFF. OF HUMAN RESOURCES MGMT
5603 FISHERS LANE-ROOM 1061
ROCKVILLE MD 20852
FedEx
4641 3490 6473
REF:
PRIORITY OVERNIGHT
MON
Deliver by:
17Jan00
cad# 0047595
14Jan00 11:31
Trk# 4641 3490 6473
Form 0201
AA
IAD
20852 -MD-US
ZM EDGA
Part# 154250-354 GTI. 8/99 ••